Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 41, 43, 46, 52, 53, 55, 57, 58 and 60-62 are pending in the application, with claim 41 being the independent claim. Claim 55 has been amended. New claims 60-62 have been added. Support for amended claims 55 and new claim 60 can be found, *inter alia*, at page 12, lines 26-31 and at page 13, lines 18-25. Support for new claims 61-62 can be found, *inter alia*, at page 50, line 28 through page 51, line12. These changes introduce no new matter as they are fully supported by the original specification as filed, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Status of U.S. applications disclosed in the specification

The Examiner has requested that Applicants update the status of all U.S. applications disclosed in the specification. (*See* Paper No. 200507, p. 2). Applicants have amended the specification herewith to update the status of all disclosed U.S. applications. Accordingly, Applicants believe the objection to be moot.

Objection to the Oath or Declaration

The Examiner has requested a new oath or declaration. (Paper No. 200507, Page 2.) Applicants note that in accordance with 37 C.F.R. §§ 1.63 and 1.67, no claim for priority to U.S. applications is required to be set forth in an oath or declaration. The only

requirement with respect to the listing of prior applications in an oath or declaration is the requirement to list foreign priority applications. 37 C.F.R. § 1.63(c)(2). Furthermore, the MPEP notes that a reference to a prior application can be inserted as the first sentence of the specification of the current application or in an Application Data Sheet (37 C.F.R. § 1.76) if applicant intends to rely on the filing date of the prior application under 35 U.S.C. §§ 119(e) or 120. *See* MPEP § 201.11; *see also* 37 C.F.R. § 1.78(a). Applicants note that the current priority claim was inserted into the first sentence of the specification in a Preliminary Amendment filed February 11, 2004. Thus, the amendment to priority has been properly claimed. *See* 37 C.F.R. § 1.78(a). Accordingly, Applicants respectfully request that the objection be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph, Written Description

Claims 52, 55, 57, 58 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement (Paper No. 200507, Page 3.)

The test for the written description requirement is whether one skilled in the art can reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); MPEP § 2163.02. The Federal Circuit has re-emphasized the well-settled principle of law that "[t]he written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [they] invented what is claimed,'" *Union Oil of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 54

U.S.P.Q.2d 1227 (Fed. Cir. 2000). Furthermore, an applicant is not required to explicitly describe the subject matter. *Unocal*, 208 F.3d at 1000; *see also* MPEP § 2163.02 ("The subject matter of the claim need not be described literally (*i.e.*, using the same terms or *in haec verba* in order for the disclosure to satisfy the description requirement.").

In particular, the Examiner alleged that there is no support in the specification as originally filed for the composition of claim 55 and that the referred passages in the specification "do not disclose the scope of the claimed invention which would encompass any peptide." (Paper No. 200507, p. 3.) Applicants respectfully disagree. However, solely to expedite prosecution, Applicants have amended claim 55 to recite that the one or more second peptides is a cytotoxic T cell (CTL)- inducing peptide or a helper T cell (HTL)- inducing peptide. Support for claim 55 can be found, *inter alia*, at page 12, lines 26-31, at page 13, lines 18-25 and page 50, lines 5-10. Thus, Applicants assert that they are in possession of the invention as recited in claim 55, and as recited in claims 57-58 which depend from claim 55. Accordingly, Applicants respectfully request that the rejection of claims 55, 57 and 58 be withdrawn.

The Examiner also alleged that there is no support in the specification as originally filed for the composition of claim 52 and that the specification does not disclose "the scope of claim 52 which encompasses other types of composition containing nonpharmaceutically acceptable carrier." (Paper No. 200507, p. 3.) Applicants respectfully traverse the rejection.

Applicants note that the Federal Circuit stated in *Univ. of Calif. v. Eli Lilly & Co.*, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997), that:

> A description of a genus of cDNAs may be achieved by means of a recitation of [1] a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or [2] of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus . . . We will not speculate in what other ways a broad genus of genetic material may be properly described . . .

Univ. of Cal., 43 U.S.P.Q.2d at 1406. Thus, the Federal Circuit has stated that the written description requirement for a claim directed to a genus of cDNAs may be satisfied by providing the sequences of a representative number of cDNAs which fall within the scope of the genus. *Id.*

In the present case, Applicants have described several types of useful carriers which are known in the art, e.g. thyroglobulin, albumins such as human serum albumin, tetanus toxoid, polyamino acids such as poly L-lysine, poly L-glutamic acid, influenza, hepatitis B virus core protein and the like. (Specification, page 43, lines 1-4.) Thus, Applicants have described a representative number of different carriers within the general category of the genus "carrier." In view of the standard for written description described above, Applicants assert that they are in possession of the claimed invention and that "a composition comprising the peptide of claim 41 and a carrier" is clearly supported in the specification such that one of skill in the art would have reasonably concluded that the inventor, at the time the application was filed, had possession of the

invention as recited in claim 52. Accordingly, Applicants respectfully request that the rejection of claim 52 be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph, Enablement

Claims 53 and 58 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. (Paper No. 200507, p. 3.)

Specifically, the Examiner asserts that "the specification does not disclose how to use the instant invention for the in vivo treatment/prevention of HBV in humans." (Paper No. 200507, pp. 3-4.) Applicants respectfully traverse the rejection as it may be applied to the amended claims.

In order for a claim to be enabled, the specification must teach one of ordinary skill in the art to make and use the invention without undue experimentation. The factors that can be considered in determining whether an amount of experimentation is undue have been set forth in *In re Wands*, 858 F.2d731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). Among these factors are: 1) the guidance provided by the specification; 2) the amount of pertinent literature; 3) the presence of working examples; and 4) the predictability of the art. The test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine. *See id.*

As stated by the Examiner, the rejection is one based on "how to use." (Paper No. 2005, p. 3.) Applicants remind the Examiner that

> [W]hen a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire score of

> that claim is sufficent to preclude a rejection for nonenablement based on how to use . . . if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention.

M.P.E.P. § 2164.01(c).

The instant claims are not limited by a recited use, so any enabled use disclosed in the specification enables the claims if the use is in keeping with their scope. Without disclaiming or disparaging any of the uses disclosed by the specification, Applicants note that the enablement requirement does not require data showing treatment efficacy or any clinical use as it would appear that the Examiner would require.

Applicants assert that the "pharmaceutical composition" of claims 53 and 58 is simply one which contains the claimed peptides as well as, for example, pharmaceutically-acceptable excipients. This composition can be used, for example, to assay the activity of peptides in transgenic mice as described in Example 8 of the specification. Thus, Applicants have enabled the claimed invention for at least one use which correlates with the claimed invention. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Rejection under 35 U.S.C. § 102

Claims 41, 43, 46, 52, 53, 55, 57, 58 are rejected under 35 U.S.C. § 102(e) as being anticipated by Seeger *et al.* (Seeger), U.S. Patent No. 5,360,714, as evidenced by Pasek *et al.* (Pasek) (Paper No. 200507, p. 6.)

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal*

Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987). MPEP § 2131. Hollingdale fails to teach every aspect of the claimed invention.

Claims 41, 43, 46, 52 and 53 are directed to an isolated peptide *less than 15 amino acids in length.* Seeger does not disclose the exact peptides as recited in the claims. As the Examiner has noted, Seeger discloses a peptide sequence which only *comprises* Applicants' claimed peptide. (*See* Seeger, col. 10, 3rd paragraph, col. 5, 3rd paragraph, cols 11-12.)

Amended claim 55 recites a composition comprising the peptide of claim 41, and one or more second peptides, wherein said isolated peptide is a CTL inducing peptide or an HTL inducing peptide. As noted above, Seeger merely discloses an HBV pol sequence which *comprises* Applicants' claimed peptide. Seeger neither teaches the exact peptide of Applicants' claimed invention, nor does Seeger teach a composition of Applicants' claimed peptide and one or more second peptides, wherein the one or more second peptides is a CTL inducing peptide or an HTL inducing peptide. Thus, Seeger does not teach all of the limitations of claim 55. Claims 57 and 58 depend from claim 55, and therefore incorporate by reference all of the limitations of claim 55. *See* 35 U.S.C. § 112, fourth paragraph. Thus, for the reasons described above, Seeger also does not teach all of the limitations of, and therefore does not anticipate, claims 57 and 58.

Based on the above, Applicants assert that Seeger does not teach all of the limitations of claims 41, 43, 46, 52, 53, 55, 57, 58. Consequently, Seeger does not anticipate these claims. As such, Applicants respectfully request that the rejection of these claims under 35 U.S.C. § 102(e) be reconsidered and withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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